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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,889	10/20/2000	Yair Feld	00/20989	7655

7590 05/15/2003

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EXAMINER	
FALK, ANNE MARIE	

ART UNIT	PAPER NUMBER
1632	9

DATE MAILED: 05/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary	Application No.	Applicant(s)	
	09/691,889	FELD ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *1-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed March 3, 2003 (Paper No. 8) has been entered. Claims 23 and 37 have been amended.

Claims 1-37 are pending in the instant application.

Claims 1-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Election was made **without** traverse in Paper No. 3.

Accordingly, Claims 23-37 are examined herein.

The following rejections are reiterated or newly applied and constitute the complete set of rejections being applied to the instant application. Rejections and objections not reiterated from the previous office action are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-37 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced on pages 2-8 of the Office Action of Paper No. 5 (mailed 10/4/02), because the specification, while being enabling for implantation of unmodified cells and *ex vivo* gene transfer, wherein the implanted cell is transformed prior to transplantation, does not reasonably provide enablement for *in vivo* gene transfer, wherein the implanted cell is transformed following implantation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants' response and the Declaration of Dr. Feld are generally persuasive with regard to the implantation of unmodified cells that meet the claim limitations as well as cells that have been genetically modified by *ex vivo* gene transfer, wherein the implanted cell is transformed prior to transplantation. However, the response is not persuasive with regard to the implantation of cells that are genetically modified by *in vivo* gene transfer, wherein the implanted cell is transformed following implantation.

At pages 9-17 of the response, Applicants point to a variety of gene therapy publications and argue that gene therapy is not unpredictable because a few successes have been reported. However, while many investigators recognize and praise the potential of gene therapy, a "potential" is not sufficient to enable the claimed invention as it relates to *in vivo* gene therapy, as it is well established that the invention must be enabled at the time of filing. A potential for the future of gene therapy does not constitute enablement, but rather is suggestive of a technology that is still undeveloped. One of skill in the art would conclude that the development of gene therapy protocols is not routine if potential successes lie predominantly in the future, not in the past. The references cited in Applicants' response and by the Examiner provide clear evidence that **intensive effort** has been applied to the development of gene therapy protocols with minimal success. None of the gene therapy methods that Applicants point to were developed using routine experimentation. In fact, the studies cited relating to VEGF gene therapy were considered breakthroughs in the field. Furthermore, if it was a simple matter to take the vectors used by others and, with routine experimentation, manipulate them and apply them in techniques for the treatment of other diseases, many successful gene therapy protocols would already exist. However, this is not the case, as evidenced by the references cited by the Examiner in Paper No. 5. Further **research** is required to accomplish these goals, not routine experimentation. Thus, the references cited by Applicants do not constitute evidence that only routine experimentation is required for the development of gene therapy protocols. On the contrary, the references clearly indicate that, in each instance, **intensive investigation** was required to develop experimental protocols. In an unpredictable art, considerable specific guidance is

needed from the specification. In the instant case, given the limited guidance in the specification with regard to the design and implementation of vectors for *in vivo* gene therapy, the lack of applicable working examples directed to administering polypeptide-encoding nucleic acids to achieve improved function within excitable tissues, and the broad scope of the claims with regard to the type of cells and vectors to be used, and the type of polypeptide-encoding nucleic acid to be used, undue experimentation would have been required for one skilled in the art to practice the claimed method over the full scope.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-27, 31, 36, and 37 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25-27, 31, 36, and 37 remain indefinite in their recitation of "capable of" because a capability is only a potential property and not an actual property. The term "capable of" implies conditionality, but the claims do not recite the conditions under which the potential property becomes an actual property. Thus, there is no requirement that gap junctions actually form or that ion channels actually form upon implantation of the cells.

Conclusion

No claims are allowed.

This application contains Claims 1-22 drawn to an invention nonelected without traverse in Paper No. 3. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, William Phillips, whose telephone number is (703) 305-3482.

Anne-Marie Falk, Ph.D.

Anne-marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER